

**MDS**  
Pharma Services

AA02981

September 15, 2003

Philip Morris USA Inc.

Re: EHCK6/01/03 (466-06): EHCSS Series K6  
Note-to-File

This is to serve as a note-to-file regarding the listing of urine mutagenicity in the primary objective in the protocol. Urine mutagenicity will be removed from the primary objective but will remain in the secondary objectives. Urine mutagenicity will be removed from the Primary Biomarker Variable Analysis and added to the Secondary Biomarker Variable Analysis. Areas of the protocol affected by this change are:

- Section 2.1 – Primary Objective (remove urine mutagenicity from the primary objective)
- 11.2 Statistical Analysis in Primary Biomarker Variable Analysis (remove urine mutagenicity) and Secondary Biomarker Variable Analysis (add urine mutagenicity).



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